



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 305N

Public Health Service

John E. Klemmer C.O. 4-7-97  
4/7/97  
PJS

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit MI 48207-3179  
Telephone: 313-226-6260  
FAX: 313-226-3076

CERTIFIED  
RETURN RECEIPT REQUESTED

April 7, 1997

WARNING LETTER  
97-DT-08

Mr. Barry Kiesel, General Manager  
Stef International  
5225 Emco Drive, Suite A  
Indianapolis, IN 46220

Re: Kerasal

Dear Mr. Kiesel:

This is in reference to the above listed product which is distributed by your firm. Kerasal, which is a combination OTC corn and callus remover ointment, is subject to the Final Rule covering Corn and Callus Remover Drug Products for Over-The-Counter Human Use, Title 21, Code of Federal Regulations, Part 358 (21 CFR 358). Any OTC drug product subject to a Final Rule that is marketed in the United States on or after the effective date must be in compliance with the final rule unless it is the subject of an approved new drug application (NDA).

The labeling for Kerasal makes claims that it is intended for the treatment of corns and calluses and that it contains salicylic acid, urea, petrolatum, glycerin, Peg-8, polysorbate-80, Peg-40 Stearate, and Peg-40 Sorbitan Peroleate in an ointment. These claims make this product a drug [Section 201 (g) of the Federal Food, Drug and Cosmetic Act (the Act)] which is subject to final regulations covering corn and callus removal products which became effective on August 14, 1991 (21 CFR 358). This product fails to meet all the requirements of the final rule since the labeling and formulation do not conform to the final rule. Therefore, this product is a "new drug" (Section 201(p) of the Act) which may not be marketed in the United States (Section 505(a)) since a NDA has not been approved for it. This product is also misbranded (Section 502(f)(1)) because the labeling fails to bear adequate directions for use and the label fails to bear an active ingredient declaration (Section 502(e)). In addition, your product is misbranded (Section 502(o)) because your firm is not registered and the product is not listed (Section 510 of the Act and 21 CFR 207.20(a)).

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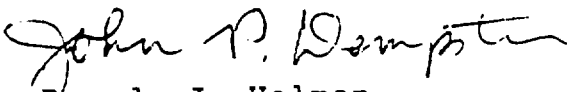
The above list of violations is not intended to be an all inclusive list of deficiencies for this product marketed by your firm. It is your responsibility to ensure that the drug products you distribute meet all requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include a seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific actions you will take to correct the violations. Your response should describe these specific actions along with an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within fifteen (15) working days, please state the reason for the delay and the time within which corrections will be completed.

Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,

  
for Brenda J. Holman  
District Director  
Detroit District

cc: Mr. Lenny Livitsky  
Chief Executive Officer  
Draxis Health Inc.  
6870 Goreway Drive  
Mississauga, Ontario L4V 1P1 CANADA

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cc: HFA-224  
JEK EF  
4-7-97 RF  
HFI-35 (purged)  
HFC-120  
HFC-210 (18-35364)  
HFC-230  
HFC-240  
HFD-300  
HFD-312 (C. Bulawka)  
JEK  
Drug Team  
IN/RP  
JAS  
FOI Team  
HFR-MW1  
WL Jkt  
WL Book

JEK  
4/7/97